# Unique Characteristics of the Home Healthcare Environment

## *IEC 60601-1-11:2010*
## *The Collateral Standard for the Home Healthcare Environment*

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# IEC 60601-1-11:2010

- This is the newest Collateral Standard to the 3rd Edition of IEC 60601-1
- Published near the end of April (last month)
- Title:
  - Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

# What does IEC 60601 consider the Home Healthcare Environment?

- Any environment that is NOT:
  - a professional healthcare facility where OPERATORS with medical training are continually available when PATIENTS are present
    - which includes emergency medical services

- regardless of whether the ME EQUIPMENT or ME SYSTEM is intended for use by a LAY OPERATOR or by trained healthcare personnel

# Electrical Supply

- Low MAINS SUPPLY requirements are broader
  - -15 % of minimum RATED voltage
  - -20 % of minimum RATED voltage for life supporting equipment
- NO PROTECTIVE EARTH connection is permitted, unless the equipment is permanently installed (hard wired) by an electrician

# Temperature and Humidity

- Home healthcare equipment is not just located in well controlled professional healthcare facilities
  - It is expected to work over the range of +5 to +40 °C and 15 to 93% RH
  - Or be marked with the lesser range
  - And be storable between uses over the range of -25 to +70 °C with up to 93% RH between uses or be marked with the lesser range

# Environmental shock

- If the equipment is intended to be used while in movement (TRANSIT-OPERABLE)
  - It needs to continue to function properly when moved from it lowest specified temperature to its highest specified temperature
  - Think of coming indoors after having been outdoors in the winter up north
  - TRANSIT-OPERABLE includes BODY-WORN equipment

# Accessibility

- In evaluating parts of the equipment that are considered to be electrically accessible
  - Use not only the ‘standard’ adult finger
  - But also the smaller ‘child’ finger (5.6 mm dia)

- Also, unless the equipment is permanently installed, only floating type applied parts are permitted

# IEC 60601-1-11 and Usability

- We have already heard about some of the unique characteristics of the user in the home healthcare environment
  - Standard requires usability evaluation to IEC 62366 including the IFU
  - OPERATOR PROFILE must include an operator with a maximum of an 8th grade education

# IEC 60601-1-11 and Usability

- The usability evaluation must include:
  - changes of controls;
  - unexpected movement;
  - potential for misconnection;
  - potential for improper operation, or unsafe use;
  - potential for confusion as to current operational mode;
  - change in the transfer of energy or substance;
  - exposure to biological materials; and
  - small parts being inhaled or swallowed

# Reusable equipment

- For equipment, their parts or ACCESSORIES that are intended for other than single use and that can become contaminated through contact with the PATIENT or with body fluids or expired gases during INTENDED USE
  - Validated cleaning, disinfection and/or sterilization instructions must be provided
  - They must be capable of being performed in the home environment or be labeled for professional reprocessing

# Enclosure Ingress

- ENCLOSURES must be at least IP21 (light rain proof)
- TRANSIT-OPERABLE, HANDHELD, and BODY-WORN equipment must be at least IP22
- These levels of ENCLOSURE stresses are considered reflective of normal use in the home healthcare environment

# Mechanical Strength

- All equipment must withstand:
  - 15 g, 11 ms shocks—three per axis (18 total)
  - 30 min random vibration per axis
    - 10 Hz to 100 Hz: 1.0 $(m/s^2)^2/Hz$;
    - 100 Hz to 200 Hz: – 3 db per octave;
    - 200 Hz to 2,000 Hz: 0.5 $(m/s^2)^2/Hz$
- These are survivability tests

# TRANSIT-OPERABLE Mechanical Strength

- Additionally, HAND-HELD equipment must withstand:
  - 30 g, 11 ms shocks—three per axis (18 total)
- For PORTABLE and MOBILE (wheeled)
  - 2 drops per specified attitude
    - for mass ≤ 1 kg, 0,25 m,
    - for mass > 1 kg and ≤ 10 kg, 0,1 m,
    - for mass > 10 kg and ≤ 50 kg, 0,05 m,
    - for mass > 50 kg, 0,01 m

# Electromagnetic Environment

- Equipment intended for the home healthcare environment must be Class B with respect to emissions
  - Such equipment is intended for ‘domestic establishments’
  - Not to interfere with TV and radio broadcast signals
- Higher immunity levels should be considered

# IEC 60601-1-11

- Lastly, JWG 6 considered issues 1, 2, 3, & 5 raised by the FDA in the development of this standard. I believe the standard adequately controls the risks associated with those issues.

# Thank you